

EXHIBIT B



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Device NUCLEUS CI522 COCHLEAR IMPLANT SYSTEM
Generic Name Implant, Cochlear
Applicant

Cochlear Americas
13059 East Peakview Avenue
Centennial, CO 80111

PMA Number P970051
Supplement Number S126
Date Received 11/14/2014
Decision Date 06/15/2015

Product Code [MCM](#)²⁴

Advisory Committee Ear Nose & Throat
Supplement Type Normal 180 Day Track
Supplement Reason Change
Expedited Review Granted? Design/Components/Specifications/Material
No

Combination Product No

Approval Order Statement

APPROVAL FOR THE CI522 COCHLEAR IMPLANT.

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Page Last Updated: 09/14/2020

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